REMARKS

The specification has been amended to correct a clerical error. Support for "ribonuclease A" can be found at page 9, line 24, for example. The term "nuclease A" does not exist.

The claim has been amended to clarify the invention.

No new matter has been added. Applicant respectfully requests entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Claim Rejection – 35 U.S.C. § 112

Claims 2-8, 10-12, and 14-15 have been rejected for failing to particularly point out and distinctly claim the invention as required in 35 U.S.C. § 112, second paragraph.

The Examiner asserts that Claims 10 and 14 are vague, indefinite and confusing in the recitation "of increasing ...." The recitation has been amended to read "for increasing ..." as the Examiner suggested.

The Examiner further asserts that the meaning of the above phrase is confusing because the recitation does not specifically and distinctly claim that this amount is in fact recovered in the process. In order to clarify the recovered amount, the recovering step is amended.

The Examiner asserts that Claims 10 and 14 are confusing and vague in the recitation of concentration of nucleases rather than the activity thereof. However, the method of measuring activity of enzymes is not well standardized and also varies depending on the specific enzyme. Exhibit A is a copy of relevant portions of the manufacture's catalogue showing the activity of ribonuclease A (which was used in Examples 1 and 2 in the present specification), which is "no less than 25 U/mg" when 1 U catalyses the formation of 1 μmole of phosphoric acid groups per minute under test conditions wherein "1.4 ml cytidine-2',3'-cyclophosphate 22.2 mmol/l (...), 0.1 ml ribonulcease (40 μg/ml), dissolved in NaCl 0.1 mol/l (EDTA 0.1 mmol/l), Temperature: 25C. Adjust to pH 7.1 and time 2 minutes." Exhibit B is a copy of relevant portions of the manufacture's catalogue showing the activity of trypsin (which was used in Example 2 in the present specification), which is "about 110 U/mg freeze-dry product (measured at 25°C using Chromozym®TPY* as a substrate ≈ about 40 U/mg freeze-dry product (measured as 25°C using benzoyl-L-arginine ethyl ester as a substrate)". Further, Exhibit C is a copy of relevant page of the manufacture's catalogue showing the activity of nuclease(r) (which was not used in the Examples in the present specification), which is 7,000-10,000 U/mg (generally 8,000 U/mg) when "one unit is

equivalent to a change in A_{260} of 1.0 after 30 minutes at pH 8.8 and 37°C of a reaction mixture of acid soluble polynucleotides from native NDA [*sic*]."

When applying the above to the present specification, the activity of enzyme in Example 1 is no less than 25 U/mg when 1 U catalyses the formation of 1 μmole of phosphoric acid groups per minute under the specific test conditions (1.4 ml cytidine-2',3'-cyclophosphate 22.2 mmol/l (...), 0.1 ml ribonulcease (40 μg/ml), dissolved in NaCl 0.1 mol/l (EDTA 0.1 mmol/l), Temperature: 25C. Adjust to pH 7.1 and time 2 minutes). The activity of enzyme in Example 2 is no less than 25 U/mg when 1 U catalyses the formation of 1 μmole of phosphoric acid groups per minute under the specific test conditions (1.4 ml cytidine-2',3'-cyclophosphate 22.2 mmol/l (...), 0.1 ml ribonulcease (40 μg/ml), dissolved in NaCl 0.1 mol/l (EDTA 0.1 mmol/l), Temperature: 25C. Adjust to pH 7.1 and time 2 minutes) plus about 110 U/mg freeze-dry product (measured at 25°C using Chromozym®TPY* as a substrate or about 40 U/mg freeze-dry product (measured as 25°C using benzoyl-L-arginine ethyl ester as a substrate). Further, if the enzyme's activity is measured in different ways such as those used for nuclease(r), the activity could be several thousands/mg. Thus, the inclusion of the activity of enzyme in the claims is likely to be confusing.

In the claimed invention, the amount of enzymes is not a critical element and one of ordinary skill in the art could readily determine an effective amount based on the disclosure of the specification. Thus, the claims have been amended accordingly.

The Examiner asserts that Claim 11 is confusing in the use of nucleases which are not specific for RNA such as deoxyribonuclease I. In response, such nuclease has been deleted from Claim 11.

The Examiner asserts that Claims 10 and 14 are substantially duplicates. However, Claim 14 has been amended by using the "a step for" language specified in 35 U.S.C. § 112, paragraph 6 which distinguishes the scope of Claim 14 from that of Claim 10.

The Examiner asserts that Claim 15 is confusing in the recitation of "to a degree achieved when the yeast-RNA containing composition is treated." In light of the Examiner's assertion, the recitation has been amended with further modifications.

The Examiner asserts that Claim 11 is vague and indefinite in the recitation of trademarks to denote the enzymes intended to be used in the process. However, as shown in Exhibit D, all of the listed enzymes are used and accepted in the art as academic terms. The Examiner's above understanding is incorrect. None of them is a trademark.

The Examiner asserts that Claims 4 and 5 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 4 and 5 have been amended.

Lastly, the Examiner asserts that Claims 2-8, 10-12, and 14-15 would be allowable upon resolution of all 35 U.S.C. § 112 issues because there would have been no motivation for one of ordinary skill in the art to modify processes of obtaining polyamine compositions by treating an RNA containing yeast composition for approximately 15-18 hours in solution with a nuclease added to a concentration of approximately 1-2 mg/ml, at approximately 25-37°C, and a pH of approximately 6-8, or with a 0.3 N alkali solution at 37°C at the time the claimed invention was made. However, no prior art reference of record teaches or even inherently suggests any process which can increase the yield of polyamine by at least 200%, followed by recovery of polyamine. The above specific conditions were used in the examples in the specification which are simply embodiments of the invention. With regard to the time period, as stated in the declaration of record by Yoshihiro Tanimoto dated July 1, 2004, in Examples 1-3, the decomposition step was conducted for 15-18 hours because they simply left the reaction materials overnight for convenience as is common practice for enzyme-related reactions, not because they thought that the time period of 15-18 hours was essential (¶2 of the declaration). The inventors specifically states that the reaction can be accomplished in "0.1 to 24 hours" on page 5, lines 8 and 19 in the specification as originally filed, and the declaration shows that the yield was increased by 206% after 0.1 hours of reaction. The invention can be characterized by comprising a decomposition step of increasing the yield of polyamine by approximately 200%-320% and a step of recovering the increased amount of polyamine. The claimed invention does not exclude any additional steps and can be used as an intermediate process.

CONCLUSION

In light of the Applicant's amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 28, 2005 By: _____

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